510(k) Summary

Non-Confidential Summary of Safety and Effectiveness

10-Jan-07

Truphatek International Ltd.
Park Poleg-C, Sapir Industrial Zone
Netanya, 42504 ISRAEL

Tel – 011-972-9-885-1155
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Official Contact: David Grey, CEO

Proprietary or Trade Name: Tru-Cable™ endoscopic fiber optic cables

Common/Usual Name: Fiber optic cables for endoscopes

Classification Name: Illuminator, fiberoptic for endoscopes
Endoscope and / or accessories

Device: Tru-Cable™

Predicate Devices: Cogent – Micro Link – K001698
Sovis Optique – K023633

Device Description:

The Truphatek Tru-Cable™ endoscopic fiber optic cables are:

- Lengths of 10 feet (3.5m)
- Diameters 3.5mm and 5.0mm
- The fiber optic cable is hermetically sealed in a closed system so that it can be sterilized or high level disinfected using most common methods.
- The cables are sold non-sterile.

The fiber optic cables are designed for use with all the most popular light source illuminators and surgical instruments that are equipped with standard endoscopic adapters. They are designed for user high level disinfection and / or sterilization by autoclave or high level disinfection may be done via Steris® or Liquid Chemicals, i.e. Cidex OPA®. The cable is rated for 100 uses when processed via autoclave.

Indications for Use --

The Tru-Cable™ endoscopic fiber optic cable is designed to transmit light for illumination purposes from a remote source to an endoscope or similar surgical instrument. It can be adapted to be compatible with a variety of illuminators.

Differences between Other Legally Marketed Predicate Devices

The Tru-Cable™ endoscopic fiber optic cables are viewed as substantially equivalent to the predicate devices – K001698 and K023633.

There are no significant differences that affect the safety or effectiveness of the intended device as compared to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Truphatek International, Ltd.
% Promedic, Inc.
Mr. Paul E. Dryden
President
3460 Pointe Creek Court, #102
Bonita Springs, Florida 34134-0354

JAN 12 2007

Re: K063309
Trade/Device Name: Tru-Cable™
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FFS
Dated: December 28, 2006
Received: December 29, 2006

Dear Mr. Dryden:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

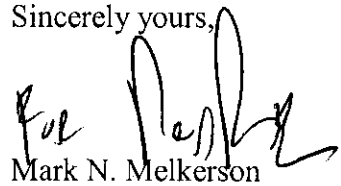
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: K063309 (To be assigned)

Device Name: Tru-Cable™

Indications for Use:

The Tru-Cable™ endoscopic fiber optic cable is designed to transmit light for illumination purposes from a remote source to an endoscope or similar surgical instrument. It can be adapted to be compatible with a variety of illuminators.

Prescription Use XX (Part 21 CFR 801 Subpart D) **or** **Over-the-counter use __** (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K063305